IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	MDL NO. 1203
THIS DOCUMENT RELATES TO: SHEILA BROWN, et al. v. AMERICAN HOME PRODUCTS CORPORATION	CIVIL ACTION NO. 99-20593 2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8445

March 31, 2010

Bartle, C.J.

Cheryl Gierke ("Ms. Gierke" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Lyle L. Grindahl, Ms. Gierke's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In October, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Azam Ansari, M.D., F.A.C.C. Dr. Ansari is no stranger to this litigation. According to the Trust, he has signed in excess of 160 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated July 16, 2003, Dr. Ansari attested in Part II of Ms. Gierke's Green Form that she suffered from

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3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

moderate mitral regurgitation, rheumatoid arthritis,[4] and an abnormal left atrial dimension.[5] Based on such findings, claimant would be entitled to Matrix B-1, Level II benefits in the amount of $95,377.[6]

In the report of claimant's echocardiogram, Dr. Ansari stated that claimant had "moderate mitral regurgitation, which on an average occupied 28% of the left atrial surface area." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See id. § I.22. Dr. Ansari also measured claimant's left atrial dimension to be "59 mm in superior-inferior axis." The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber

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4. Under the Settlement Agreement, the presence of rheumatoid arthritis requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)iii)d).

5. Dr. Ansari also attested that claimant suffered from mild aortic regurgitation and New York Association Functional Class II symptoms. These conditions, however, are not at issue in this claim. Moreover, Dr. Ansari made a handwritten notation on the Green Form that claimant's ejection fraction was "60-65%." It, however, appears that claimant has conceded that her ejection fraction is not at issue.

6. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). An abnormal left atrial dimension is one of the complicating factors needed to qualify for a Level II claim.

view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b).

In January, 2004, the Trust forwarded the claim for review by Jeremy I. Nadelmann, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Nadelmann concluded that there was no reasonable medical basis for Dr. Ansari's finding that claimant had moderate mitral regurgitation explaining that "[t]he degree of [mitral regurgitation] is at most mild. There are no sustained jets of [mitral regurgitation] seen. The [mitral regurgitation] jets mapped out on the echo tape are inaccurate and include background noise and scatter." Dr. Nadelmann also measured claimant's left atrial dimension as 5.0 cm in the apical four chamber view and 3.7 cm in the parasternal long-axis view and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had an abnormal left atrial dimension. In support, Dr. Nadelmann explained that Dr. Ansari's "measurement is inaccurate, in that he is measuring from the mitral leaflets during diastole, when the valve is open and at the other end, his caliper is in the pulmonary vein."[7]

Based on Dr. Nadelmann's findings, the Trust issued a post-audit determination denying Ms. Gierke's claim. Pursuant to

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7. Dr. Nadelmann also disagreed that claimant has rheumatoid arthritis, but he did not opine as to whether there was a reasonable medical basis for the attesting physician's finding.

the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[8] In contest, claimant submitted a supplemental opinion from Dr. Ansari, who confirmed his findings of moderate mitral regurgitation and an abnormal left atrial dimension, and attached still frames from claimant's echocardiogram that purportedly demonstrated these conditions. Claimant also argued that the auditing cardiologist's finding of mild mitral regurgitation should be disregarded because Dr. Nadelmann eyeballed the regurgitant jet as opposed to taking actual measurements. Finally, claimant contended that the audit process is flawed because there are additional answer choices on the Report of the Auditing Cardiologist that do not appear on the Green Form.[9]

The Trust then issued a final post-audit determination, again denying Ms. Gierke's claim. Claimant disputed this final

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8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Gierke's claim.

9. In contest, claimant also contended that the auditing cardiologist should be required to declare under penalty of perjury that the information contained in the Report of the Auditing Cardiologist is correct to the best of his or her knowledge. In making this assertion, however, claimant ignores that Dr. Nadelmann signed an Attestation Form dated February 8, 2004 and a Certification dated January 2, 2005, averring that his findings were true and correct. See generally Audit Rule 7.

determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Gierke's claim should be paid. On February 9, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 4470 (Feb. 9, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on November 10, 2005, and claimant submitted a sur-reply on December 2, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[10] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical

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10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Advisor Report are now before the court for final determination. See id. Rule 35.

The issues presented for resolution of this claim are whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's findings that Ms. Gierke had moderate mitral regurgitation and an abnormal left atrial dimension. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Gierke reasserts the arguments that she made in contest, namely, that the auditing cardiologist eyeballed the regurgitant jet as opposed to taking measurements and that the Report of the Auditing Cardiologist contains additional answer choices that are not on the Green Form.[11] Claimant also submitted a new verified opinion from Dr.

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11. Claimant also argues that, as the court has removed certain auditors for undisclosed conflicts of interest, it gives rise to the inference that the auditing cardiologists are not always correct. Claimant also questions whether the auditing cardiologist who reviewed her claim was one of the disqualified auditors. Pursuant to PTO No. 4245, for any claim that was audited by a disqualified auditing cardiologist, the claimant was (continued...)

Ansari, who reiterates his findings of moderate mitral regurgitation and an abnormal left atrial dimension, and attached one color still frame from claimant's echocardiogram. Claimant further contends, among other things, that the auditing cardiologist's findings are not supported by verifiable evidence. Additionally, claimant asserts that, as the Green Form definition does not reference low velocity, non-sustained, or background noise, the auditing cardiologist is attempting to alter the Settlement Agreement's definition of mitral regurgitation.[12] Finally, claimant renews her argument that the Trust's audit system is flawed and unfair to claimants.

In response, the Trust argues that there is no reasonable medical basis for Ms. Gierke's claim because the auditing cardiologist concluded that the attesting physician relied on "'jets' of short turbulence duration that are overtraced to include backflow, non-regurgitant flow, background noise, and scatter." The Trust also asserts that the supplemental report of Dr. Ansari fails to establish a reasonable medical basis for her claim because it "merely offer[s] the same

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11. (...continued)
notified and provided an opportunity to have his or her claim re-audited by an independent auditing cardiologist. See PTO No. 4245 (Dec. 15, 2004). As claimant received no such notification, the auditing cardiologist who reviewed her claim was not one of the disqualified auditors.

12. In addition, Ms. Gierke submits her claim should be payable on Matrix A-1 because the auditing cardiologist determined that she did not have rheumatoid arthritis. Given our disposition regarding this claim, we do not need to reach this issue.

measurements and still shots of the July 16, 2003 echocardiogram" that were found to be deficient by the auditing cardiologist. The Trust further argues that eyeballing is an accepted echocardiographic methodology. Finally, the Trust contends that the additional possible responses included in the Report of the Auditing Cardiologist have no effect on the outcome of claims, and that claimant's broad-based criticisms of its administration of the claims process are beyond the scope of the show cause proceedings.

In her sur-reply, claimant reiterates her assertion that the auditing cardiologist altered the definition of mitral regurgitation by referencing low velocity, background noise, backflow, and displaced blood. Claimant also renews her argument that the Settlement Agreement does not provide for eyeballing the level of regurgitation.[13]

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Abramson found that:

> In reviewing the transthoracic echocardiogram, my visual estimate is that

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13. Ms. Gierke also claims that the Trust's audit of her claim lacked consistency, quality, and integrity because the Certification of the Audit misrepresents her Green Form responses. We reject this assertion because claimant ignores the Trust's letter dated November 9, 2005, notifying Ms. Gierke that it inadvertently included page 2 of a Certification for another claimant and provided her with the correct Certification.

> there is only mild mitral regurgitation. I measured the mitral regurgitant jet and the left atrial area (in the same frame) in five representative cardiac cycles .... These ratios are 6%, 5%, 3%, 7%, and 7%, all of which are considerably less than 20%, which is consistent with mild mitral regurgitation. The three tracings performed by the sonographer on the tape include low velocity color flow areas which are not part of the mitral regurgitation jet and thus artificially inflate the RJA/LAA ratio.

Dr. Abramson also concluded that there was a reasonable medical basis for the attesting physician's finding that claimant had an abnormal left atrial dimension.[14]

In response to the Technical Advisor Report, claimant argues that Dr. Abramson's conclusions lack technical credibility as they are not substantiated by either exhibits or attachments. Claimant also submits that Dr. Abramson has altered the Green Form definition of mitral regurgitation by referencing low velocity flow in her analysis. Finally, claimant contends that she has met her burden of proving that there is a reasonable medical basis for her claim based on the verifiable documentation provided by Dr. Ansari.[15]

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14. Given our ultimate disposition regarding claimant's level of mitral regurgitation, however, we need not address whether claimant has met her burden in proving that she had an abnormal left atrial dimension.

15. Claimant further contends that Dr. Abramson lacks the necessary credentials to be a Technical Advisor as set forth in Audit Rule 32. We disagree. We appointed Dr. Abramson to assist the court in reviewing certain claims in the show cause process after finding that she possessed the requisite skills and expertise. See PTO No. 3212 (Jan. 14, 2002).

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, we disagree with claimant that Dr. Abramson did not substantiate her findings or that the auditing cardiologist's findings lack verifiable evidence. To the contrary, Dr. Abramson determined that claimant's level of regurgitation was only mild, and that tracings on the echocardiogram tape improperly included low velocity flow that artificially inflated the RJA/LAA ratio. Similarly, the auditing cardiologist concluded that claimant, at most, had mild mitral regurgitation and that there were deficiencies in the measurements relied upon by claimant. As explained by the auditing cardiologist, the measurements were inaccurate and "include[d] background noise and scatter." On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.[16]

We also disagree with claimant's assertion that low velocity flow is considered mitral regurgitation. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion

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16. For these reasons as well, the still frames submitted by claimant are insufficient to establish a reasonable medical basis for her claim.

of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-15, 21-22, 26 (Nov. 14, 2002). Here, Dr. Nadelmann concluded that the mitral regurgitant jets measured on claimant's echocardiogram included "background noise and scatter", and Dr. Abramson concluded that there were "low velocity color flow areas." Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form answer of moderate mitral regurgitation.[17]

Moreover, we disagree with claimant's arguments concerning the required method for evaluating a claimant's level of valvular regurgitation. Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having moderate mitral regurgitation, it does not specify that actual measurements must be made on an echocardiogram. As we explained in PTO No. 2640, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology."

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17. Although claimant asserts that the Green Form defines mitral regurgitation as including blue, green or mosaic signals, nothing in this citation reflects or alters this court's previous determination in PTO No. 2640 that improperly characterizing low velocity flow as mitral regurgitation is an unacceptable practice. As claimant did not adequately contest the determination of both the auditing cardiologist and the Technical Advisor that this is precisely what occurred in the review of claimant's echocardiogram, claimant cannot establish a reasonable medical basis for her claim.

Id. at 15. Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of mitral regurgitation be made to determine if a claimant qualifies for Matrix Benefits. There is no basis for such a revision and claimant's argument is contrary to the "eyeballing" standards we previously have evaluated and accepted in PTO No. 2640.[18]

Finally, we disagree with claimant's assertion that the Trust's audit system is unfair to claimants. It is claimant's burden in the show cause process to show why she is entitled to Matrix Benefits. See Audit Rule 24. The audit and show cause process, as approved by this court, provided claimant with notice and an opportunity to present her evidence in support of her claim.[19]

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we affirm the Trust's denial of Ms. Gierke's claim for Matrix Benefits and the related derivative claim submitted by her spouse.

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18. Claimant's argument also fails because the Technical Advisor, although not required to, made specific measurements of the level of mitral regurgitation, which further establishes that claimant is not entitled to Matrix Benefits

19. We also reject claimant's argument that there are inconsistencies between the possible answers on the Green Form and the Report of the Auditing Cardiologist. Although the Report of the Auditing Cardiologist includes additional selections for the level of mitral and aortic regurgitation, these choices have no bearing on whether a claimant qualifies for Matrix Benefits.